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WASHINGTON, D.C. 20231

ATTENTION: APPLICATION BRANCH

Sir:

Transmitted herewith for filing is the patent application of

Inventor(s): **George A. Lopez, M.D. and Virgil R. Laul**

For: **MEDICAL CONNECTOR**

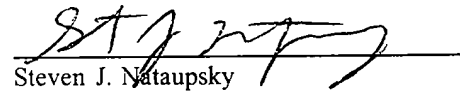
Enclosed are:

- (X) 9 sheet(s) of drawing.
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- (X) This application is a continuation of U.S. Patent Application Serial No. 08/473,524, filed June 7, 1995, which was a continuation of U.S. Patent Application Serial No. 08/424,237, filed April 19, 1995, which was a file wrapper continuation of U.S. Patent Application Serial No. 08/279,247, filed July 21, 1994, which was a continuation of U.S. Patent Application Serial No. 08/020,098, filed February 19, 1993, now issued U.S. Patent No. 5,344,414, which was a continuation of U.S. Patent Application Serial No. 07/346,193, filed January 9, 1987, which was a divisional of U.S. Patent Application Serial No. 06/606,679, filed May 3, 1984, now abandoned, which was a continuation-in-part of U.S. Patent Application Serial No. 06/543,248, filed October 19, 1983, now abandoned, which was a continuation-in-part of U.S. Patent Application Serial No. 06/460,585, filed January 24, 1983, now abandoned and priority is claimed under 35 U.S.C. § 120.
- (X) A copy of Declaration from prior application is enclosed.
- (X) Preliminary Amendment is enclosed.
- (X) A small entity statement was filed in the prior application, and such status is still proper and desired.
- (X) Incorporation by Reference. The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

CLAIMS AS FILED

FOR	NUMBER FILED	NUMBER EXTRA	RATE	FEE
Basic Fee			\$395	\$395
Total Claims	7 - 20 =	0 ×	\$11	\$
Independent Claims	2 - 3 =	0 ×	\$41	\$
TOTAL FILING FEE				\$395

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Steven J. Nataupsky
Registration No. 37,688
Attorney of Record

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NEWPORT BEACH, CALIFORNIA 92660-8016

(714) 760-0404

FAX (714) 760-9502

INTERNET WWW.KNOB.COM

LOUIS J. KNOBBE*
DON W. MARTENS**
GORDON H. OLSON**
JAMES B. BEAR
DARRELL L. OLSON*
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OF COUNSEL
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JAPANESE PATENT ATTY
KATSUHIRO ARAI
EUROPEAN PATENT ATTY
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Attorney Docket No. : ICUMM.6FCFC4
Applicant(s) : George A. Lopez, M.D. et al.
For : MEDICAL CONNECTOR
Attorney : Steven J. Nataupsky
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Mailing Label No. : EM351210766US
Date of Deposit : April 8, 1998

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copy of Power of Attorney Form and copy of Assignment; copy of Declaration
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Don King

PNC-1162:sls
012098

**ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231**

ATTENTION: APPLICATION BRANCH

Sir:

Transmitted herewith for filing is the patent application of

Inventor(s): **George A. Lopez, M.D. and Virgil R. Laul**

For: **MEDICAL CONNECTOR**

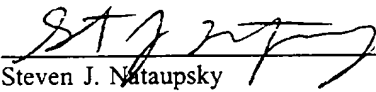
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Steven J. Nataupsky
Registration No. 37,688
Attorney of Record

PNC-1160 sls/rdc2
040898

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	George A. Lopez et al.)	Group Art Unit 3306
)	
Appl. No.	:	UNKNOWN)	
)	
Filed	:	HEREWITH)	
)	
For	:	MEDICAL CONNECTOR)	
)	
Examiner	:	J. Yasko)	
)	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Preliminary to considering the above-captioned application on the merits, please amend the application as follows:

IN THE SPECIFICATION:

Please replace the first sentence with the following: "This application is a continuation of U.S. Patent Application Serial No. 08/473,524, filed June 7, 1995, which was a continuation of U.S. Patent Application Serial No. 08/424,237, filed April 19, 1995, which was a file wrapper continuation of U.S. Patent Application Serial No. 08/279,247, filed July 21, 1994, which was a continuation of U.S. Patent Application Serial No. 08/020,098, filed February 19, 1993, now issued U.S. Patent No. 5,344,414, which was a continuation of U.S. Patent Application Serial No. 07/346,193, filed January 9, 1987, which was a divisional of U.S. Patent Application Serial No. 06/606,679, filed May 3, 1984, now abandoned, which was a

Appl. No. : UNKNOWN
Filed : HERewith

continuation-in-part of U.S. Patent Application Serial No. 06/543,248, filed October 19, 1983, now abandoned, which was a continuation-in-part of U.S. Patent Application Serial No. 06/460,585, filed January 24, 1983, now abandoned."

IN THE CLAIMS:

Please cancel Claims 1-40.

Please add the following new claims:

41. **(NEW)** A medical connector for selectively transferring a fluid from one location to another, said connector comprising:

a first connector member having a proximal end;

a resilient, pre-slit resealable septum positioned at said proximal end of said first connector member, said septum presenting a flat, swabbable outer surface;

a second connector member for connection to said first connector member for establishing a fluid flow between said members, said second connector member having a body with a hollow proximal end, said body adapted for extension over said proximal end of said first connector member, and a hollow tube, said hollow tube connected to said body, said hollow tube having a free end positioned within said hollow proximal end of said body, whereby said end of said hollow tube is recessed within said proximal end of said body, and whereby when said body is extended over said proximal end of said first connector member, said hollow tube penetrates said septum.

42. **(NEW)** The medical connector in accordance with Claim 41, wherein said body is generally cylindrical in shape.

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43. (**NEW**) The medical connector in accordance with Claim 41, wherein said hollow tube has a second end in communication with a fluid line extending from said second connector member.

44. (**NEW**) The medical connector in accordance with Claim 41, further including means for selectively locking said first connector member to said second connector member in a position in which said hollow tube extends through said septum.

45. (**NEW**) A two-piece medical connector for selectively establishing flow of medication, comprising:

a port member, said member having an end with a resilient, pre-slit resealable and swabbable septum extending thereacross; and

an engaging member for selective engagement with said port, said engaging member having a body defining a hollow chamber, said body having an end with an opening therein leading to said chamber, a hollow tube having a free end, said hollow tube extending from said body such that said free end of said hollow tube is positioned in said chamber, said opening sized so that said body may be selectively extended over said port member, whereby said hollow tube penetrates said septum for establishing a flow of medication between said engaging member and said port, and wherein said septum reseals when said hollow tube is removed.

46. (**NEW**) The medical connector in accordance with Claim 45, wherein said engaging member has a fluid line extending therefrom, said fluid line in communication

Appl. No. : UNKNOWN
Filed : HEREWITH

with a passage extending through said hollow tube from said free end of said hollow tube.

47. (**NEW**) The medical connector in accordance with Claim 45, wherein said port member has a chamber positioned distal of said septum and a fluid line extending in communication with said chamber.

REMARKS

By this Amendment, Applicant has canceled claims 1-40 and added new claims 41-47. Since the pending claims are believed allowable over the prior art, Applicant respectfully requests a notice of allowance.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 8, 1998

By: SAJ

Steven J. Nataupsky
Registration No. 37,688
Attorney of Record
620 Newport Center Drive
Sixteenth Floor
Newport Beach, CA 92660
(714) 760-0404

PNC-1149 'rdc1
040898

MEDICAL CONNECTOR

RELATED PATENT APPLICATIONS

06/07/80 12:55:00
This application is a continuation-in-part application of U. S. patent application Serial No. 06/543,248, filed October 19, 1983, and entitled "Medical Connector System," which was a continuation-in-part application of U. S. patent application Serial No. 06/460,585, filed January 24, 1983, and entitled "Device for Intravenously Introducing Medication Into a Patient," (now abandoned). These previously filed patent applications, which are incorporated herein by reference and made part of this patent application, disclose the experimental versions of this invention. These experimental versions are also disclosed herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to medical connectors used in the treatment of the injured or sick, and in particular to a connector for introducing medication into a patient in a safe, convenient way.

2. Background Discussion

It is a common practice in treating patients, particularly patients who must be cared for under emergency conditions, with medication introduced into the patient intravenously. An intravenous solution, commonly referred to as parenteral liquid, is fed from a container holding this liquid. The liquid flows through tubing into a needle which has been inserted into the patient's vein. The needle is taped securely to the patient's body and is not likely to

pull loose if the patient moves. Medication needed to sustain the life of the patient, for example, drugs which maintain the blood pressure of the patient at the desired level, are added to the parenteral liquid. The conventional practice is to introduce the medication through a second needle inserted into a sealed entry port in the tubing through which the parenteral liquid flows.

One problem with this conventional practice is that the needle may be pulled loose from the sealed port relatively easily. Such accidental removal of the needle from the sealed port can have very serious consequences and could even lead to the death of the patient. Although many hospitals require nurses to tape the needle securely to the tubing, this is not always done, because taping is a burdensome and time consuming task.

A second problem with the conventional practice is needle sticks. From time to time a nurse in attempting to insert the needle into the sealed entry port will accidentally stick himself or herself with the needle. This often occurs under emergency conditions when the nurse is under pressure to complete this task as quickly as possible. Not only is the accomplishment of the task delayed, but the nurse must stop working and have a blood test performed. Such a test is needed in case the nurse becomes infected, because the hospital will be responsible financially. Consequently, needle sticks not only result in increased hospital cost, but are a possible life treating event to the nurse.

A third problem with the conventional practice is infection. All too often a patient's life is seriously endangered by bacteria gaining entry into a patient's blood stream and infecting the patient. In a vast number of cases it is unknown how the bacteria gain entry. We have observed conditions in hospitals and identified that one likely way the bacteria gain entry is by contamination of the needle inserted into the sealed entry port. This happens when the nurse notices that the needle has been pulled loose and simply reinserts it even though it may now have on its surface bacteria picked up by direct contact with, for example, the patient's bedding. Another possible way that bacteria may gain entry into the patient's

blood stream is through contamination of the tape used to hold the needle to the connector.

MAJOR FEATURES OF THE INVENTION

The problems discussed above present a serious health hazard to patients and their nurses. The present invention eliminates these problems and provides a medical connector which is both safe and convenient to use.

There are several features of this invention which contribute to its safety and convenience, no single one of which is solely responsible for these desirable attributes. Many of these features were present in our experimental versions of the invention, which were improved after testing. Without limiting the scope of this invention as expressed by the claims, its more prominent features will now be discussed briefly. After considering this discussion, and particularly after reading the section of this application entitled DETAILED DESCRIPTION OF THE DRAWING, one will understand how the features of this invention provide the attributes of safety and convenience.

One safety feature of this invention is the use of a cap member to enclose the needle to be inserted into the sealed entry port structure. This cap member fits snugly over the entry port structure, connecting with the port structure in a male-female mating relationship. The needle pierces the seal when the cap member is seated on the port structure. This needle is housed deep within a cavity in the cap member that terminates in an open mouth into which the sealed end of the port structure fits. This open mouth is narrow in width so that the finger of the nurse or patient cannot fit into the cavity and contact the needle. Since the needle is so mounted within the cap member, the likelihood of bacterial contamination is avoided or reduced and the nurse is protected against accidental needle sticks.

A second safety feature is provided by the wall design of the cap member and port structure. These walls are of preferably

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cylindrical configuration and engage each other like a telescope. The interior surface of the wall of the cap member slides over the exterior surface of the wall of the mating port structure, with these walls engaging each other to guide the needle into the center of the seal. This ensures that the needle does not scrape against the inside surface of the wall of the port structure. Particles scraped from this wall could make their way into the patient's blood stream and result in death. This potentially lethal condition is inherent in the design of conventional devices. But the connector of this invention, with the guideway wall design of the cap member and port structure, ensures that the needle is directed into the center of the seal so that it avoids scraping against the inside surface of the wall of the port structure. This guideway wall design also permits the nurse quickly to connect the cap member to the port structure. This makes the connector of this invention not only more convenient to use, but in emergencies, enables the nurse to administer medication to a patient faster than with conventional devices and doing it without the danger of needle sticks.

A third safety feature of the invention is that a locking mechanism detachably secures the cap member to the port structure. Because of this feature, movement of the patient does not result in accidental removal of the needle from the seal. Although many different types of locking mechanisms may be employed, the preferred one provides a sound upon locking engagement of the cap member and port structure. We have devised such a locking mechanism which produces a sound such as a "click." This "click" is an audible signal which tells the nurse that the cap member is locked safely to the port structure and cannot be accidentally jarred loose by movement of the patient.

Several embodiments of the invention illustrating all the features of this invention will now be discussed in detail. These embodiments show the invention being used for administering medication intravenously to a patient. This invention may also be used to administer medication to a patient in other ways, for example, intracranially or intraperitonally.

BRIEF DESCRIPTION OF THE DRAWING

The drawing, wherein like numerals indicate like parts, depicts four embodiments of this invention in which:

Figure 1 is a schematic view illustrating administering medication intravenously to a patient in accordance with conventional practice.

Figure 2 is a cross-sectional view of a piggyback connector for introducing parenteral liquid and medication intravenously to the patient shown in Figure 1.

Figure 3 is a perspective view of the first embodiment of the medical connector of the present invention which employs a slip-on/twist lock type means for securing the cap member to the port structure.

Figure 4 is a cross-sectional view of the connector shown in Figure 3 taken along line 4-4 of Figure 3.

Figure 4a is a perspective view showing how the cap member prevents needle sticks.

Figure 5 is a perspective view of the second embodiment of the medical connector of the the present invention which employs a snap-on type means for securing the cap member to the port structure.

Figure 6 is a cross-sectional view of the connector shown in Figure 5 taken along line 6-6 of Figure 5.

Figure 7 is an exploded perspective view of the third embodiment of the medical connector of the present invention which employs a snap-on type means for securing the cap member to the port structure.

Figure 8 is a side elevational view, with sections broken away, of the embodiment shown in Figure 7. In this Figure 8 the handle of the locking mechanism attached to the cap member just engages the lip of the port structure.

Figure 9 is the same view as shown in Figure 8, except the handle of the locking mechanism is flexed and just about to snap into locking engagement with the lip of the port structure.

Figure 10 is the same view as shown in Figures 8 and 9, except the handle of the locking mechanism is now engaging the lip of the port structure in the locking position.

Figure 10a is the same view as shown in Figures 8, 9 and 10, except the handle of the locking mechanism is flexed to permit removal of the cap member from the port structure.

Figure 11 is a top plan view of the cap member.

Figure 12 is a bottom view of the handle of the locking mechanism shown in Figures 8 through 11.

Figure 13 is a side elevational view of the handle of the locking mechanism.

Figure 14 is a side elevational view of the cap member with the handle of the locking mechanism removed.

Figure 15 is a top plan view of the cap member with the handle of the locking mechanism removed.

Figure 16 is an enlarged cross-sectional view of a portion of the hinge of the locking mechanism.

Figure 17 is an enlarged cross-sectional view of the position of the handle just prior to being secured to the cap member.

Figure 18 is a cross-sectional view similar to that shown in Figure 17 depicting the handle coupled to the cap member.

Figure 19 is a cross-sectional view taken along line 19-19 of Figure 18.

Figure 20 is a perspective view showing the medical connector of Figure 7 having one end coupled to a tube extending from a patient's arm and another end coupled to a tube extending from a container holding medication.

Figure 21 is a perspective view of a medical connector like that shown in Figure 7, except the port structure has the lip which engages the handle of the locking mechanism as an integral part of a conventional piggyback connector.

Figure 22 is a schematic view showing a medical connector of the type shown in Figure 7 designed to introduce medication into a patient's chest.

Figure 23 is a perspective view of a fourth embodiment of the medical connector of this invention which employs a slip-on/twist lock type means for securing the cap member to the port structure.

Figure 24 is an enlarged cross-sectional view taken along line 24-24 of Figure 23, showing the cap member being connected to the sealed entry port structure.

DETAILED DESCRIPTION OF THE DRAWING

Conventional Connector System

As shown in Figures 1 and 2, the current way of intravenously introducing parenteral liquid into a patient is by the conventional feeding system 10. This feeding system 10 includes a container 12 for the parenteral liquid, a tube 14 extending from the container and connected to a Y or "piggyback" connector 16, and a tube 18 from the piggyback connector to a needle (not shown) inserted into a vein of the patient. The needle is taped to the patient so that movement of the patient will not result in the needle being pulled from the patient's vein.

As best illustrated in Figure 2, medication from the container 20 is introduced through the piggyback connector 16 into the parenteral liquid flowing through the feeding system 10. This piggyback connector 16 consists of two tubular conduits 22 and 24 which merge into a third tubular conduit 26. The tubing 14 from the container 12 of parenteral liquid is inserted into the inlet port 28 of the conduit 22 and secured in position, for example, by an adhesive which bonds the external surface of this tube to the internal wall surface of the conduit. There is a stop 30 which limits the extent to which this tube 14 can be inserted into the conduit. In a similar fashion, the tube 18 is secured to the outlet port 32 of the piggyback connector. This tube 18 is inserted into the outlet port 32 until it abuts a stop 34 in the internal wall of the conduit. This tube 18 is secured by an adhesive to the internal wall of the conduit 26.

The sealed entry port structure of the conventional feeding system 10 is provided by the branch conduit 24 which has a standard latex rubber seal 36 at its inlet port 38 to seal this port. Consequently, bacteria cannot enter the piggyback connector 16 via the inlet port 38 because of the seal 36. This seal 36 is of conventional design and includes coaxial annular aprons 40 and 42 which fit over the conduit wall 24a and grip the external and internal wall surfaces to hold the seal securely to the conduit 24. A suitable seal may be obtained from the West Company of Phoenixville, Pennsylvania.

The medication is introduced into the parenteral liquid flowing through the piggyback connector 16 by a needle 44 which is inserted through the central part of the seal 36 into the branch conduit 24. This needle 44 is connected by a suitable connector 46 to a tube 48 which is connected to the container 20 (Figure 1) for the medication. As parenteral liquid flows through the piggyback connector 16 into the inlet port 28 and out the outlet port 32, the medication is drawn into this stream of liquid, flowing from the container 20 via the tube 48 and through the open tip or end 44a of the needle 44 into the parenteral liquid.

After studying Figures 1 and 2, the several problems associated with the conventional practice can now be more fully understood. If the patient moves, for example, rolls or moves his or her arm, the needle 44 may be pulled from the seal 36. If this occurs, the latex seal 36 has sufficient resiliency to close off the hole in the seal produced by the needle 44. The parenteral liquid will continue to flow into the patient's system, but the necessary medication is no longer being introduced into it. The consequences of this condition are very grave and, if this condition is unnoticed by the nurse, it could result in the death of the patient or serious complications in the patient's treatment. Even if the nurse notices that the needle 44 has been removed from the seal 36 and reinserts it into the seal, it is possible that the needle has been contaminated with bacteria. The use of such a contaminated needle 44 is unacceptable, but nevertheless this sometimes happens. The needle 44 may

be taped to the conduit 24, and many hospitals instruct nurses to do this. When this task is done, the needle 44 is secured, but cannot be conveniently removed and then reinserted. And even when taping the needle 44, if this is not done carefully, the needle may still be contaminated by the nurse touching the needle or the tape being contaminated. Also, because the nurse holds the conduit 24 with one hand while inserting the needle 44, the nurse may accidentally stick the needle directly into the hand holding this conduit, or stick the needle through the conduit wall 24a into this hand.

These problems associated with the conventional practice are eliminated by the several different embodiments of this invention disclosed hereinafter.

First Embodiment of the Invention

As illustrated in Figures 3 and 4, the first embodiment of this invention, connector 49, employs a cap member 50 housing deep within the needle 44. As will be discussed in greater detail hereinafter, the cap member 50 is secured by a slip-on/twist lock type of locking mechanism to the piggyback connector 16 so that movement of the patient does not result in the needle 44 being pulled from the seal 36. The parenteral liquid is introduced via the conduit 24, and the conduit 22 carries the seal 36 that covers the inlet port 28. In this embodiment, this sealed conduit 28 constitutes the entry port structure 27. The cap member 50 is detachably secured to the entry port structure 27, with the needle 44 penetrating the seal center of the seal 36 when the cap member 50 mates with the port structure 27.

The cap member 50 comprises a cylindrical connector section 56 having a hollow interior forming the chamber or cavity 52 housing the needle 44. This needle 44 is disposed lengthwise along the longitudinal axis of the cavity 52 and is centrally located. The cavity 52 has an open mouth 52a which allows the cap member to be seated over the port structure 27. The mouth 52a, however, is constricted so that, as illustrated in Figure 4a, it prevents the little finger of a typical adult user from being inserted into the

cavity 52. The tip or end 44a of the needle is safely displaced inwardly from the open mouth 52a so that even if the user intentionally inserted his or her finger into the open mouth, the tip of the needle would not stick this finger. Typically, the open mouth 52a has a maximum width of no greater than about one centimeter, and the minimum distance between the mouth 52a and the tip 44a is about one centimeter.

The locking mechanism includes the threads 69a formed in the end 54 of the interior cavity wall 55 and the threads 69b in the exterior wall of the conduit 22. These threads 69a and 69b engage upon connection of the cap member 50 to the port structure 27 by screwing the cap member to the conduit 22. The top of the cap member 50 has a pair of outwardly extending wings 58 which facilitate screwing the cap member 50 to the conduit 22. As this is done, the interior wall 55, sliding over the exterior surface of the conduit 22, guides the needle 44 so that it penetrates the center of the seal 36. To further ensure that the needle 44 penetrates the center of the seal 36, the threads 69b could be lowered further beneath the seal so that the cap member would fit telescopically over the conduit 22 and then be screwed into position. Thus, the cap member 50, serving as the female component, and conduit 22, serving as the male component, mate in a male-female relationship, with the needle 44 always being housed safely within the center of the cavity in an unexposed condition and positioned to pierce the center of the seal 36.

A spindle 59 is provided to enable the cap member 50 to be screwed onto the port structure 27 without twisting the tube 48. This spindle 59 is received within an opening 61 within the cap member 50. The body of the spindle 59 has a cylindrical neck section with a groove 63 in an end which protrudes from the opening 61. The cylindrical body expands outwardly slightly to provide a shoulder 65 which engages a stop 66 when the spindle 59 is placed in the opening, and a TRU seal C-ring 67 is received in the groove 63 to hold the spindle in position but allowing the cap member to revolve about the spindle as it is screwed onto the port structure

Along the longitudinal axis of the spindle 59 is a passageway 60. The tube 48 from the container 20 holding the medication is inserted into the one end 60a of the passageway 60 and is bonded to the internal surface of this passageway, for example, by means of an adhesive. The other end 60b of the passageway terminates in a threaded connector section 62 to which the needle 44 is secured. This needle has an adapter 64 which has an internal thread which engages the threads of the connector section 62. The needle 44 extends outwardly from this adapter 64. Thus, the needle 44 is held secure to the piggyback connector 16, penetrating the center of the seal 56 with its point 44a safely displaced away from the inside wall 55 of the conduit 22.

This connector 49 embodies many of the features of this invention. For example, the cap member 50 safely houses the needle 44, and the threads on the guiding walls provide means for detachably securing the cap member to the port structure without taping. But it has several components, and therefore is costly to manufacture, it is time consuming to screw the cap member 50 to the port structure, and it does not provide an audible signal when the cap member is safety secured to the port structure. This later feature is provided by the second and third embodiments of this invention.

Second Embodiment of the Invention

The second embodiment of the present invention, connector 71, is shown in Figures 5 and 6. In this embodiment a cap member 70, similar to cap member 50, is simply snapped onto the piggyback connector 16. The snap-on type locking mechanism of this connector 71 is easier to use and less costly to manufacture than the slip-on/twist type of the first embodiment.

In this embodiment, the cap member 70 includes a hollow cylindrical element 72 which carries on its exterior two clips 74 which have catch tips 76 that snap into a groove 78 in the external wall of the conduit 22. The clips 74 are mounted by hinges 75 to the element 72, and are integral with the element 72. A plug

assembly 80 carries the tubing 48 and the needle 44, which is mounted on an adapter 64 such as shown in Figure 4. This plug assembly 80 is glued or otherwise bonded to the open end of the cylindrical member 72. The cap member 70, including clips 74 and hinges 75, are molded from the same material, for example, nylon, which is a material having the desired resiliency.

To attach the cap member 70, one simply slips the member 70 over the conduit 22. The clips 74 bend outwardly slightly and, when the catch tips 76 of the clips are opposite the groove 78, the clips snap in place as shown in solid lines in Figure 6. The centrally mounted needle 44 is guided into the center of the seal 36 by the cap member 70, which, like a telescope, slides over the tubular conduit 22. There is shoulder 82 which serves as a stop to limit the movement of the cap member 70. This shoulder 82 brings the catch tips 76 of the clips into registration with the groove 78. The hinges 75, being of the same material as the clips 74, provide an internal bias or spring action due to the resiliency of the material from which these clips and hinges are made. Consequently, the clips 74 snap into a locking position, locking the cap member to the conduit 22 when the catch tips 76 are in registration with the groove 78. To release the cap member from the piggyback connector 16, the clips 74 are simply depressed and the cap member 70 is removed.

One of the features of the slip-on type locking mechanism is that with one simple inwardly push the needle 44 is inserted directly into the center of the seal 36 and the cap member is locked to the port structure. Another feature of this connector 71 is that when the tips 76 of the clips snap into the groove 78 a "click" sound is made by the tips striking the body of the cap member. With repeated use, however, the hinges 75, due to internal stress produced in the nylon material, lose some of their spring action. Consequently, the tips 76 are not held with sufficient force in the groove 78, nor do they strike the body of the cap member to produce the desired "click" sound. Moreover, the material will eventually crack along the flex line of the hinge and a break will occur. The reliability

of this connector 71 is substantially improved by the third embodiment of this invention which employs a unique locking mechanism.

Third Embodiment of the Invention

As shown in Figure 7, the third embodiment of this invention, connector 90, includes a sealed port structure 91 and a cap member 92 having a locking mechanism 94 for detachably securing the cap member 92 to the port structure 91. The cap member 92 is similar to the cap members of the other embodiments and houses within its cavity 92a (Figure 8) the needle 44. The cavity 92a has a tapered side wall 93 to better direct the needle 44 into the center of the seal 36.

The port structure 91 is a tubular conduit 102 having, at one end, a reduced diameter nipple 104 over which the seal 36 fits and, at the other end, a tapered barrel 103. The seal 36 is of the same type employed in conventional devices such as shown in Figure 2. Material is removed from the barrel 103 to reduce cost. This results in the formation of flutes 103a in the barrel 103. At the base of the barrel 103, adjacent the end of the port structure 91, is an annular, disk-like piece which provides a lip 106. When the cap member 92 is placed over the port structure 91, a handle 96, which is a component of the locking mechanism 94, engages this lip 106. The handle 96 is hinged to the body 98 of the cap member by a two component hinge 100.

As best shown in Figures 14 and 15, a hook 114 is one component of the hinge 100 and the other component of the hinge is a crossrod 108 (Figure 18) carried by the handle 96. The hook 114 projects outwardly from the body 98 of the cap member and has adjacent to it a ramp 116, which as shown in Figure 18, holds the crossrod 108 when the handle 96 is attached to the body of the cap member. A section of the crossrod 108 is cut away to provide a miter slot 118 which engages the ramp 116.

The handle 96 is best shown in Figures 12 and 13. It has a pair of spaced apart plates 110 and 112 extending downwardly from the underside of the handle and the crossrod 108 is disposed between

these plates, with the opposed ends of the crossrod being integral with the plates. Opposite the crossrod 108 and parallel to it is a third plate 120, which is integral with the underside of the handle 96 and is at a right angle to and connects with the forward ends of the plates 110 and 112. Disposed on the underside of the handle 96 between the catch tip 122 and the plate 120 is a clapper bar 126. The clapper bar 126 produces the "click" sound when it strikes the body 98 of the cap member. This clapper bar 126 extends away from the plate 120 at a right angle and is integral, at one end of the handle, with the catch tip 122 and, at its opposite end, with the plate 120. The leading edge 124 of the catch tip 122 is beveled to facilitate the slippage of this tip up and over the lip 106 which is also beveled. At the point where the clapper bar 126 merges with the inside of the catch tip 122, there is a notch 128, which, as shown in Figure 10, receives the lip 106 when the handle 96 is in the locking position. At the rearend of the handle 96 is a leaf spring 130 which has one end free and its opposed end integral with the handle 96. At the free end of the leaf spring 130 are two spaced apart tracks 132 and 134 (Figure 12). When the handle 96 is attached to the body of the cap member as shown in Figures 8 through 10, a finger 136 on the body 98 of the cap member is received within the channel 138 between the tracks 132 and 134. On the underside of the handle 96 are two downwardly projecting reinforcing strips 140 and 142 (Figure 12) which provide structural rigidity to the handle.

The way in which the handle 96 is pivotably connected to the cap member 92 by the two component hinge 100 is illustrated by Figures 16 through 19. To attach this handle 96 to the body 98 of the cap member, first one positions the handle over the body of the cap member opposite the hook 114 and then moves the handle into contact with the cap member so that the crossrod 108 touches the rearend of the ramp 116. The spring 130 is depressed at this time. Next, the handle 96 is moved towards the left, as shown in Figure 17, with the crossrod 108 sliding up the ramp 116 until it engages the leading edge 140 of the hook 114. The dimension between the edge

142 of the ramp 116 and the edge 140 of the hook 114 is less than the diameter of the crossrod 108. Consequently, the hook 114 must flex slightly upwardly in a counterclockwise direction, as viewed in Figure 17, until the crossrod 108 clears the edge 142 of the ramp and snaps into the position shown in Figure 18. The hook 114 thus returns to the unflexed condition shown in Figure 18, wrapping around the crossrod 108. The miter slot 118 then engages the edge 142 of the ramp, with this edge abutting the junction 118a of the slot 118 (Figure 18). The ramp 116 thus holds the crossrod 108 in position, preventing the handle from becoming dislodged from the hook 114 and preventing the handle 96 from tilting to-and-fro about its longitudinal axis. When the handle 96 is so mounted to the body 98 of the cap member, the finger 136 slips into the channel 138 between the tracks 132 and 134 and holds the rearend of the handle so that it does not tend to move laterally. The handle 96 is, however, free to pivot about the hinge 100.

Unlike the hinges 75 of the second embodiment of this invention, the two component hinge 100 does not break due to fatigue. Thus, in accordance with one feature of connector 90, the handle 96 may be moved between a locked position (Figure 10) and unlocked position (Figure 8) as often as one wishes without breaking. At the same time, the handle 96, coating with the body 98 of the cap member 92, generates a "click" sound when the cap member is locked to the port structure 91. This "click" sound, as best illustrated in Figures 9 and 10, occurs when the handle 96 moves between the flexed position shown in Figure 9 and the locked position shown in Figure 10.

The connector 90 is highly reliable under actual hospital working conditions, and the way connector 90 is used is best shown in Figures 8 through 10a. First, the nurse inserts the end of the port structure carrying the seal 36 into the open mouth 93 of the cap member 92 to bring the lip 106 into engagement with the catch tip 122 of the handle 96 as shown in Figure 8. As this is done, the tapered side wall 93 of the cap member and the tapered barrel 103 slide along each other to direct the needle 44 into the center of the seal 36. Simultaneously, the beveled edge 124 of the catch

tip rides over the beveled lip 106 until the lip just engages the underside edge of this tip as shown in Figure 9. This causes the handle 96 to rotate in a clockwise direction as viewed in Figure 9, with the crossroad 108 turning while in the grasp of the hook 114. There is enough clearance between the miter slot 118 and the edge 142 of the ramp to allow the crossrod to turn sufficiently so the catch tip 122 clears the lip 106. Thus the handle 96 pivots about the hinge 100, depressing the spring 130. With the handle 96 and lip 106 in this position and the spring 130 depressed, as soon as the lip 106 clears the edge of the catch tip 122, the spring rotates the handle in a counterclockwise direction, moving it to the position shown in Figure 10 with ample force so that the clapper bar 126 strikes the body 98 of the cap member to produce the "click" sound. This "click" sound is the audible signal which the nurse may rely upon to indicate that the cap member 96 is locked to the port structure 91. Under certain hospital conditions, particularly in the intensive care unit where there is not a great deal of light, this is an important feature because it provides additional assurance that the cap member 92 is locked to the port structure 91.

As shown in Figure 10, with the handle 96 in this locked position, the needle 44 has penetrated the central portion of the seal 36, directed by the tapered sidewalls of the cavity 92a and the barrel 103. Medication now flows through the connector 90 into the patient. Note, the handle 96 is not depressed as the cap member 92 is slid over the port structure 91. To remove the cap member 92, the handle 96 is depressed, moving it to the position shown in Figure 10a. With the handle 96 in this position, the cap member 92 is pulled off the port structure 91.

Except for the seal 36, the connector 90 is made entirely of a transparent plastic. The use of a transparent plastic is preferred because this allows the nurse to see that the needle 44 is correctly inserted into the seal 36, and thus provides additional safety. Also, the use of plastic makes the connector 90 a low cost, disposable item. The plastic most suitable is a polycarbonate made by Cyrolite Industries in Azusa, California sold under the tradename Cyrolite.

This plastic, which is commonly employed to make medical devices, has been approved for such uses by the United States Federal Drug Administration.

The connector 90 is particularly adapted to be used in a variety of different applications. For example, as illustrated in Figure 20, it may be connected directly in line with a container 144 of medication to be supplied intravenously to a patient. In this instance, the cap member 92 has a tube 146 extending from it which has at its one end a male component 148 of a conventional luer lock connector. This male component 148 engages and locks with a mating female luer component 150 attached to the end of a line 146 extending from the container 144. In a similar manner, the port structure 91 has extending from it a tube 154 which has at its end a female luer component 158 of a second luer lock connector. The male component 156 of this second luer lock connector is attached to the end of a tube 160 that is connected to a needle inserted into the vein of the patient. The luer lock connectors may be obtained from Burron Medical, Inc. in Bethlehem, Pennsylvania.

Figure 21 illustrates the connector 90 integrated into a conventional piggyback connector 162. The branch line 164 from the piggyback connector 162 has attached to it and integral therewith the port structure 91 including the lip 106 that engages the catch tip 122 of the locking mechanism 94. Thus, a conventional feeding system 10 employing a piggyback connector may be modified by simply including a lip 106 adjacent the seal 36. This lip 106 will then serve as the site for detachably connecting the cap member 92 to the piggyback connector 162.

The connector 90, as shown in Figure 22, also lends itself to be used with central venous catheters which are inserted into the chest of the patient. Frequently, patients under home care use such catheters, and consequently, even simpler and safer devices and techniques must be employed. However, a serious problem with such catheters is the way the ends of the lumens or tubes 166 and 168 extending from the patient are sealed. Presently, the ends of these tubes 166 and 168 are sealed using conventional luer locks.

When it is time for the patient or the nurse to introduce medication into the catheter, an intermediate portion of the tubes 166 and 168 must be clamped while being connected to the source of medication so that air is not drawn into the blood stream of the patient. Any large intake of air into the patient's blood stream will seriously injure or even kill the patient. With children, even a small amount of air may be fatal. That is why clamps are used to close off the tubes 166 and 168 until the connection is made with the source of medication. This results in the tubes 166 and 168 wearing out, requiring that they be repaired. Not only is this a dangerous system, but it is extremely inconvenient for the patient or nurse to use.

As illustrated in Figure 22, the connector system 90 overcomes these difficulties by simply having at each of the respective ends of the tubes 166 and 168 port structures 91. When the patient needs medication, he or she simply connects two of the cap members 92 to the respective port structures 91, and when finished, disconnects the cap members. The medication is fed by the needles 44 through the seals 36 and into the respective tubes 166 and 168. The cap members 92, when detached, withdraw the needles 44 from the seals 36, which are self sealing. Thus, the nurse does not need to clamp off the tubes 166 and 168 nor is periodic repair of the tubes required. Since the seal 36 is self-sealing, upon removal of the cap member 92 there is no danger of air being drawn through the port structure 91 into the patient's blood stream. Consequently, connector 90 is both safer and more convenient to use than the conventional central venous catheters.

The connector 90 is also adapted to be used repeatedly without damaging the seal 36. Thus it is even more suitable for such applications as illustrated in Figure 22 than conventional devices, because of the accuracy with which the needle 44 may be repeatedly directed into the center of the seal 36. When the needle 44 is repeatedly stuck into and withdrawn from the seal 36, the seal will have numerous holes in it and begin to develop a "swiss cheese" like appearance. Eventually, a core is cut away from the seal by

several of these holes interconnecting, rendering the seal useless because it is no longer self-sealing. Consequently, the seal would have a very short life. By carefully controlling the dimensions of the molds used to make connector 90, the cap member 92 and port structure 91 will be precision made parts. Consequently, with repeated use, the needle 44 will essentially always penetrate the same hole in the seal 36, thus avoiding the "coring" problem.

Fourth Embodiment of the Invention

The fourth embodiment of this invention, the connector 170, is illustrated by Figures 23 and 24. In connector 170 the port structure 172 is similar to that shown in the other embodiments except it has a pair of pins on opposite sides of its body 178 which co-act with J-type slits 180 and 182 in the sidewall of a cap member 183 housing the needle 44. These J-type slits 180 and 182 are opposed to each other and provide a guideway for the pins 174 and 176 which slide along these slits as the port structure 172 matingly engages the cap member 183.

To use this connector system 170, the nurse aligns the port structure 172 with the open mouth 183a of the cap member so that the pins 174 and 176 are in alignment with the entryway to the J-type slits 180 and 182. Then the nurse pushes the port structure 172 into the open mouth 183a, sliding the port structure into the cavity within the cap member 183. The pins 174 and 176 first engage the entryway of the J-type slits 180 and 182 and then slide along the slits until they reach the base of the slits. At this point, the nurse twists or rotates the cap member 183 and port structure 172 in counter-rotating directions so that the pins 174 and 176 will then slide respectively into the hooks 180a and 182a of the slits and be secured. This embodiment does not provide an audible signal upon locking the cap member 183 to the port structure 172, but is very economical to manufacture.

Function of the Cap Member and Port Structure

As will be appreciated from the above description, the cap member provides several functions in a single structure. (We will no longer refer by number to any one of the components of the invention since we are now discussing in general how the cap member and port structure function to provide the attributes of safety and convenience.) First, the cap member surrounds the needle and provides a housing in which the needle is lodged safely so that needle sticks are avoided. Second, because the needle is so lodged within the housing, if the nurse did, for example, lay the cap member on the patient's bed, the needle would not come into direct contact with the bedding which might be infested with harmful bacteria. Thus, this arrangement of the needle deep within the cavity in the cap member provides protection for the patient against bacterial contamination and protection for the nurse against accidental needle sticks.

The port structure also provides more than one function. First, it serves as the site to attach the cap member, and, by means of a simple locking element such as a lip, thread, groove, pin or the like, provides an economical way to modify the conventional piggyback connector so that it may be used with the cap member. Second, the combination of a self-sealing seal and adjacent element that locks with the cap member provides a simple way to modify connectors so that they have enhanced safety and convenience.

The cap member and port structure function in combination to direct the needle into the center of the seal, lock these pieces together, and enable quick connection. The nurse or patient simply aligns the sealed end of the port structure with the open mouth of the cap member and pushes the two pieces together. The internal wall of the cap member and the exterior wall of the port structure engage to align the two pieces so that their respective axes coincide, guiding the needle into the center of the seal as they are pushed together. Consequently, the needle does not scrape the inside wall of the port structure so that particles of plastic are not introduced into the patient's blood stream and the coring problem is virtually

eliminated. The cap member and port structure each carry elements of a locking mechanism which engage and lock the pieces together when the needle has pierced the seal, preventing accidental disconnect. Although other geometric forms may be employed, quick connection is facilitated by the cylindrical configuration of the walls of the cap member and port structure and the circular open mouth of the cavity. In particular, the first through third embodiments of this invention are very quickly connected because no extra step is required to align the cap member and port structure. All that the nurse need do is insert the port structure into the open mouth without any special concern for their relative positions, and, when using the second and third embodiments, simply push these two pieces together until the locking mechanism engages. When using the first or fourth embodiments, the extra step of rotating the two pieces relative to each other is required to engage the locking mechanism. When using the forth embodiment, the pins must also first be aligned with the entryways to the J-slits prior to pushing the port structure into the cavity in the cap member.

Because of the features embodied in the cap member and port structure, this invention may be used under normal hospital conditions without creating any additional work for the nurse, while substantially reducing the likelihood of harm to the patient due to carelessness and protecting the nurse against infection and making his or her job easier and faster.

SUMMARY

In summary: Our connector is safe because (a) the needle is recessed deeply within the cap member and, therefore, is not likely to be contaminated by bacteria, (b) the cap member and port structure upon engagement guide the needle into the center of the seal, avoiding scraping particles from the inside wall of the port structure, (c) the cap member, housing the needle safely within it, protects the nurse against needle sticks, and (d) the locking of the cap member and port structure together prevents accidental

disconnects and (e) the "click" signals the nurse when the connector system is locked securely in position. Our connector is convenient to use because (a) the walls of the cap member and port structure, interacting with each other, provide a guideway for quick connection, (b) the locking mechanism eliminates the burdensome and time consuming task of taping, and (c) the connector is very simple to use so that it is ideal for home care of patients.

SCOPE OF THE INVENTION

060040" 42695060 The above description presents the best mode contemplated of carrying out the present invention as depicted by the four embodiments disclosed. The combination of features illustrated by these embodiments provide the safety and convenience of this invention. This invention is, however, susceptible to modifications and alternate constructions from the embodiments shown in the drawing and described above. Consequently, it is not the intention to limit it to the particular embodiments disclosed. On the contrary, the intention is to cover all modifications and alternate constructions falling within the scope of the invention as generally expressed by the following claims:

1. In a system for feeding medication from a remote source through tubing means into a patient, a connector including:

(a) port means attached to the tubing means through which the medication is introduced into the tubing means,

(b) means sealing the port means which is penetrated by a needle that is in communication with the source of medication and through which the medication flows into the tubing means, and

(c) a cap member detachably secured to the port means, said cap member having a cavity therein in which the needle is safely housed by being recessed deep within the cavity so that it will not likely be contaminated by bacteria or stick a user of the connector.

2. The connector of Claim 1 wherein the cavity has an open mouth into which the port means is manually inserted when the cap member is secured to the port means, said open mouth being constricted so that only the very tip of the little finger of a typical adult user will fit into the cavity.

3. The connector of Claim 2 wherein the needle has its tip displaced inwardly a substantial distance from the open mouth so that, even if said user intentionally inserted his or her finger into the open mouth, the tip of the needle would not stick said finger.

4. The connector of Claim 3 wherein the maximum width of the open mouth does not exceed about one centimeter and the tip of the needle is displaced inwardly from the open mouth a minimum distance of about one centimeter.

5. The connector of Claim 3 wherein the cavity is formed by a first wall element which surrounds the needle and the port means is formed by a second wall element, said first and second wall elements engaging when the cap member is secured to the port means to serve as guide means for directing the needle into the sealing means.

6. The connector of Claim 5 wherein the needle is disposed lengthwise along the longitudinal axis of the cavity and aligned to penetrate the central portion of the sealing means and not scrape against the inside of the second wall element as the cap member is secured to the port means.

7. The connector of Claim 6 wherein the cavity is tapered inwardly from the open mouth.

8. The connector of Claim 1 having snap-on type means for detachably securing the cap member to the port means.

9. The connector of Claim 1 having slip-on/twist means for detachably securing the cap member to the port means.

10. The connector of Claim 1 made of a transparent plastic material.

11. The connector of Claim 1 wherein the port means is an integral part of a conventional piggyback connector and includes means which lock with means on the cap member.

12. The connector of Claim 1 including means for producing a sound when the cap member and port means are securely attached to each other, thereby providing an audible signal that this condition exists.

13. The connector of Claim 1 wherein the sealing means is of the self-sealing type and the cap member and port means are precision made so that with repeated use the needle will penetrate the sealing means at essentially the same point each time it is inserted through the sealing means.

14. The connector of Claim 1 wherein the cap member and port means engage in a male-female mating relationship when secured together, with the cap member serving as the female member and the port means serving as the male member.

15. In a system for feeding medication from a remote source through tubing means into a patient, a connector including:

(a) port means attached to the tubing means through which the medication is introduced into the tubing means,

(b) means sealing the port means which is penetrated by a needle that is in communication with the source of medication and through which the medication flows into the tubing means, said sealing means being of the self sealing type so that a hole in the sealing means produced by penetration of the needle is closed off upon withdrawal of the needle, and

(c) a cap member detachably secured to the port means, said cap member having a cavity therein in which the needle is safely housed by being recessed deep within the cavity so that it will not likely be contaminated by bacteria or stick a user of the connector, said cavity having an open mouth into which the port means is manually inserted when the cap member is secured to the port means, said open mouth being constricted so that only the very tip of the little finger of a typical adult user will fit into the cavity, with said needle being disposed lengthwise along the longitudinal axis of the cavity and aligned to penetrate the central portion of the sealing means, and having its tip displaced inwardly a substantial distance from the open mouth so that, even if the user intentionally inserted his or her finger into the open mouth, the tip of the needle would not stick said finger.

16. The connector of Claim 15 wherein the maximum width of the open mouth does not exceed about one centimeter and the tip of the needle is displaced inwardly from the open mouth a minimum distance of about one centimeter.

17. The connector of Claim 15 wherein the cavity is formed by a first cylindrical wall element which surrounds the needle and the port means is formed by a second cylindrical wall element having an open end which is sealed by the sealing means, said wall elements being coaxially aligned and engaging in a male-female mating relationship when the cap member is secured to the port means, with the interior surface of the first wall element, sliding over the exterior surface of the second wall element whereby said wall elements serve as guide means for directing the needle into the central portion of the sealing means so that the tip of the needle does not scrape particles from the inside surface of the second wall element.

18. The connector of Claim 17 wherein cap member and port means are precision made so that with repeated use the needle will penetrate the sealing means at essentially the same point each time it is inserted through the sealing means.

19. The connector of Claim 15 including means for producing a sound when the cap member and port means are securely attached to each other, thereby providing an audible signal that this condition exists.

20. In a system for feeding medication from a remote source through tubing means into a patient, a connector including:

(a) port means attached to the tubing means through which the medication is introduced into the tubing means,

(b) means sealing the port means which is penetrated by a needle that is in communication with the source of medication and through which the medication flows into the tubing means, said sealing means being of the self sealing type so that a hole in the sealing means produced by penetration of the needle is closed off upon withdrawal of the needle, and

(c) a cap member detachably secured to the port means, said cap member having

- (i) a cavity therein in which the needle is safely housed by being recessed deep within the cavity so that it will not likely be contaminated by bacteria or stick a user of the connector, said cavity having an open mouth into which the port means is manually inserted when the cap member is secured to the port means,
- (ii) said open mouth being constricted so that only the very tip of the little finger of a typical adult user will fit into the cavity, with said needle being disposed lengthwise along the longitudinal axis of the cavity and aligned to penetrate the central portion of the sealing means, and having its tip displaced inwardly a substantial distance from the open mouth so that, even if the user intentionally inserted his or her finger into the open mouth, the tip of the needle would not stick said finger,
- (iii) said cavity being formed by a first wall element which surrounds the needle and the port means being

formed by a second wall element having an open end which is sealed by the sealing means, said wall elements being coaxially aligned and engaging in a male-female mating relationship when the cap member is secured to the port means, with the interior surface of the first wall element sliding over the exterior surface of the second wall element, whereby said wall elements serve as guide means for directing the needle into the central portion of the sealing means so that the tip of the needle does not scrape particles from the inside surface of the second wall element,

- (iv) With said cap member and port means being precision made so that with repeated use the needle will penetrate the sealing means at essentially the same point each time it is inserted through the sealing means.

✓ 21. The connector of Claim 20 including means for producing a sound when the cap member and port means are securely attached to each other, thereby providing an audible signal that this condition exists.

22. A cap member for connecting a source of medication to a tubular conduit, comprising:

a connector section having a hollow interior which forms a cavity having an open end adapted to receive the tubular conduit, said end being constricted so that a finger ~~will~~ not fit into the cavity, and

a needle disposed lengthwise within the cavity and of a length such that its tip is displaced inwardly from the open end of the cavity, said needle being secured at the end opposite said tip to the connector section and adapted to be placed in communication with the source of medication.

23. The cap member of Claim 16 wherein the connector section is cylindrical and the needle is disposed along the longitudinal axis of said cylindrical connector section.

✓24. The cap member of Claim 23 wherein the cylindrical connector section is taped^{ed} inwardly from the open end of the cavity.

25. The cap member of Claim 22 wherein the open mouth has a maximum width no greater than about one centimeter and the tip of the needle is at least one centimeter from the open mouth.

26. The cap member of Claim 25 wherein the connector section and tubular conduit engage in a male-female mating relationship when attached to each other.

27. The cap member of Claim 22 including snap-on type means for detachably securing said cap member to the tubular conduit.

✓28. The cap member of Claim 22 including slip-on/twist lock type of means for detachably securing said cap member to the tubular conduit.

✓29. The cap member of Claim 22 including means to produce a sound when said cap member is secured to the tubular conduit.

30. A connector for introducing medication into a patient comprising a pair of tubular members adapted to engage in a mating relationship and be detachably secured together, one of said members having a sealed port and the other having deeply recessed therein a needle which penetrates the central portion of the port when the tubular members engage in said mating relationship, and means which produce a sound when the tubular members are secured together to provide an audible signal that said members are safely locked together.

31. The connector of Claim 30 wherein the tubular members are secured together by snap-on type means.

32. The connector of Claim 30 wherein the tubul^ar members are secured together by slip-on/twist lock type means.

33. The connector of Claim 30 wherein the tubular members are precision made so that with repeated use, the needle will penetrate the sealed port at essentially the same point each time the tubular members engage.

✓34. A connector for introducing medication into a patient comprising,

a
a first tubul^r member having one end adapted to be placed in communication with the patient and an opposed end including a sealed port through which the medication is introduced, said first tubular member having lip means adjacent the sealed port; a second tubular member having an open end and being adapted to receive in its open end the sealed port when the tubular members engage in a male-female mating relationship, said second tubular member

- (i) having on its exterior the first component of a two component hinge means and
- (ii) recessed therein a needle which is disposed generally along the longitudinal axis of the second tubular member and has its one end secured to the closed end of the second tubular member and its opposed end displaced inwardly from the open end and free to penetrate the central portion of the sealed port when the tubular members engage in said mating relationship; and

clip means for detachably securing the first and second tubular members together, said clip means including

- (i) a handle element having catch tip means at one end adapted to engage and lock unto the lip means when the tubular members engage,
- (ii) spring means near the end of the handle element opposite the catch tip means,
- (iii) the second component of the hinge means disposed between the opposed ends of the handle, said second component being coupled to the first component to allow the handle to pivot about the hinge means between a locked position with the catch tip means grasping the lip means and an unlocked position disengaging the catch tip means and the lip means when the handle is depressed by an externally applied force to bias the spring means to return the handle to its locked position as soon as the externally applied force is removed.

(iv) and clapper bar means on the handle which is lifted away from the exterior of the second tubular member when the handle is depressed and which strikes said exterior upon release of the handle to produce a sound which indicates that the handle is in the locked position.

35. In a medical connector system in which a port at the end of a tubular conduit is provided with a seal that is penetrated by a needle through which medication is to be introduced into the system, said seal being self-sealing upon withdrawal of the needle, the improvement comprising means adjacent the seal which engages a locking mechanism on a cap member carrying the needle and detachably secures the cap member to the tubular conduit.

✓36. The improved connector system of Claim 35 wherein the securing means comprise threads which screw into threads on the cap member.

37. The improved connector system of Claim 35 wherein the securing means comprise an annular member that provides a lip which locks with the locking mechanism.

✓38. The improved connector system of Claim 35 wherein the securing means are slit means which engage pins on the cap member.

✓39. The improved connector system of Claim 35 wherein the securing means comprise groove means which locks with the locking mechanism.

✓40. The improved connector system of Claim 35 including means to produce a sound when the locking mechanism has secured the cap member to the tubular conduit.

ABSTRACT OF THE DISCLOSURE

Disclosed is a connector for introducing medication into a patient in a safe, convenient way. It comprises a pair of plastic tubular members adapted to be manually pushed together to engage in a male-female relationship, and a locking mechanism that detachably secures the members together. The male member has a sealed entry port at its end, and the female member safely houses within it a needle which centrally pierces the seal of the port upon engagement of the members. Preferably, the locking mechanism provides a "click" sound when it locks the members together.

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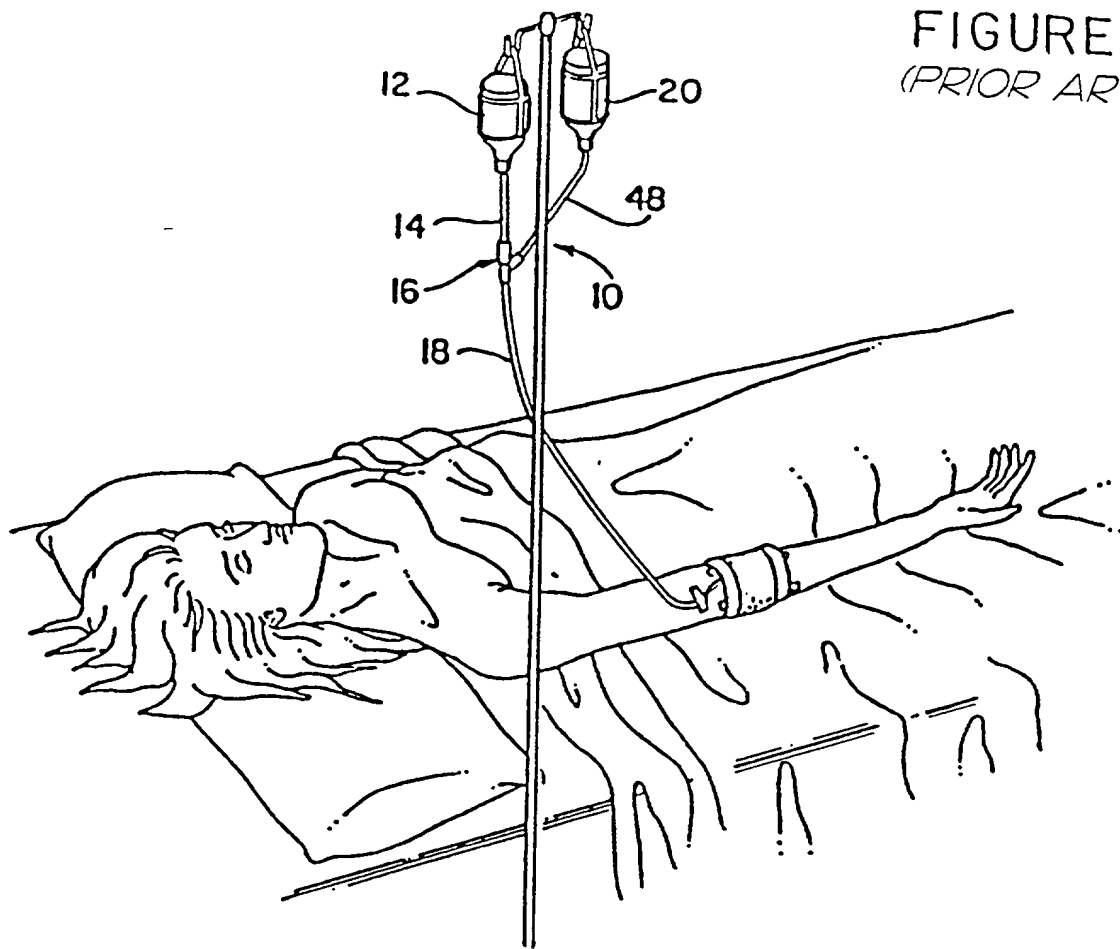


FIGURE 1
(PRIOR ART)

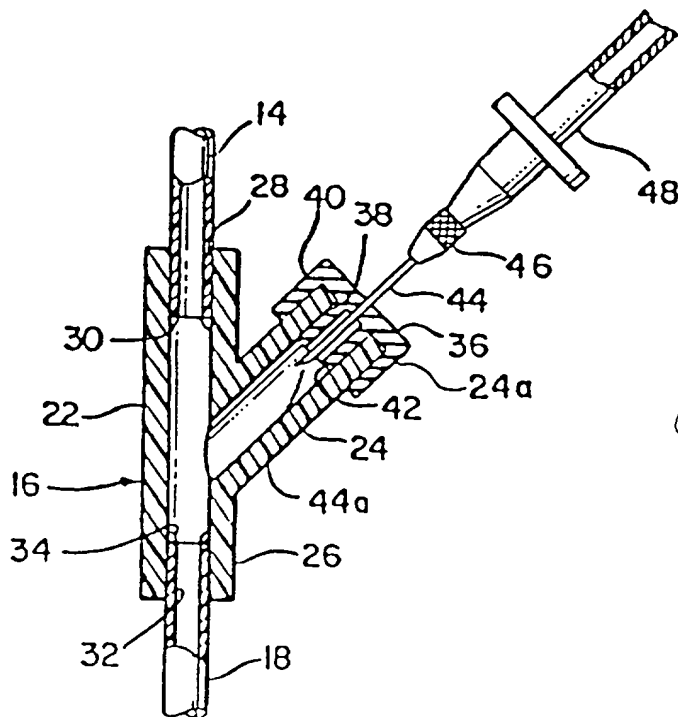


FIGURE 2
(PRIOR ART)

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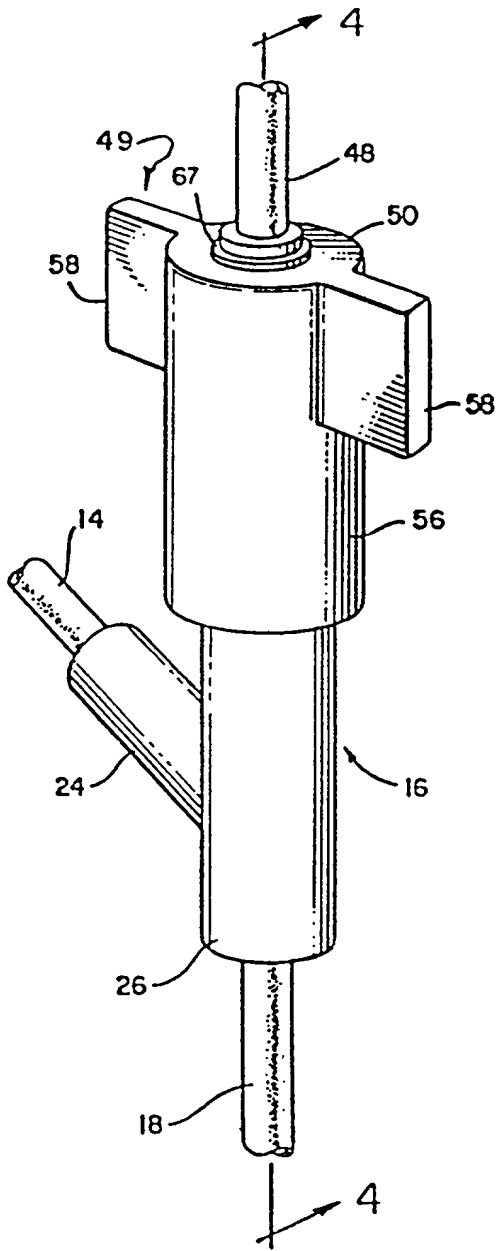


FIGURE 3

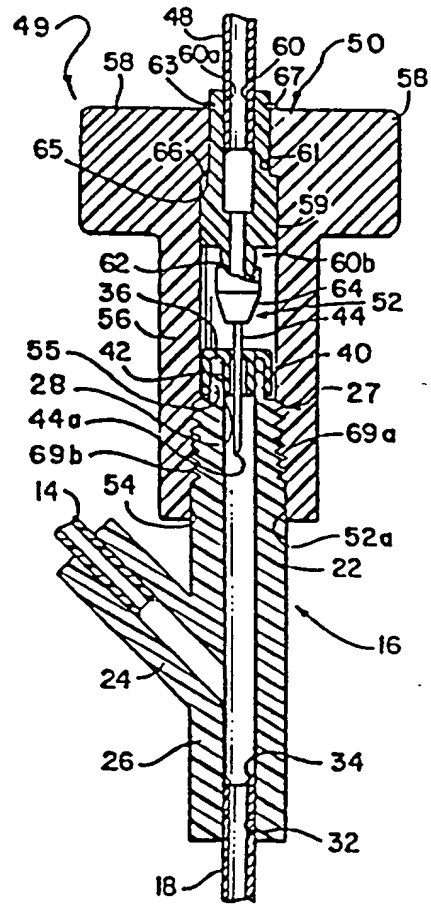


FIGURE 4

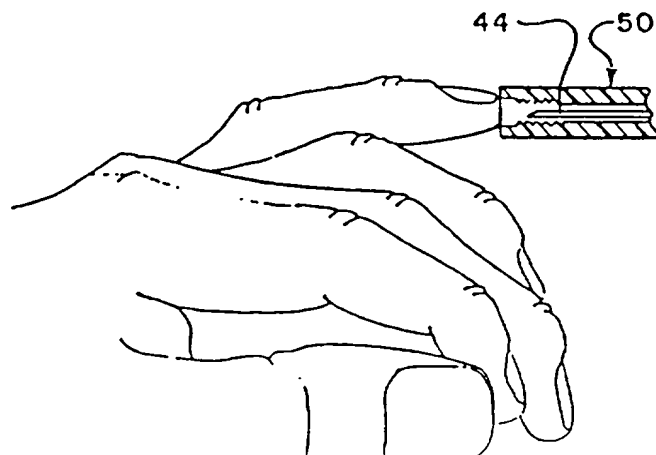


FIGURE 4a

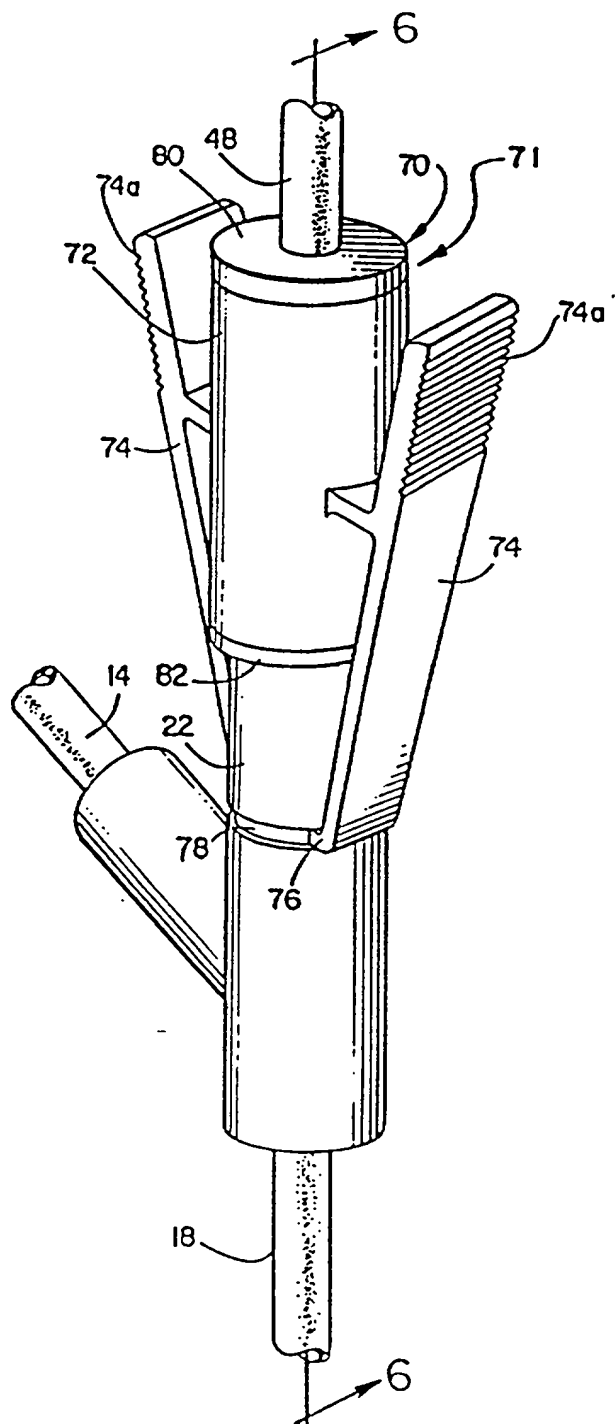


FIGURE 5

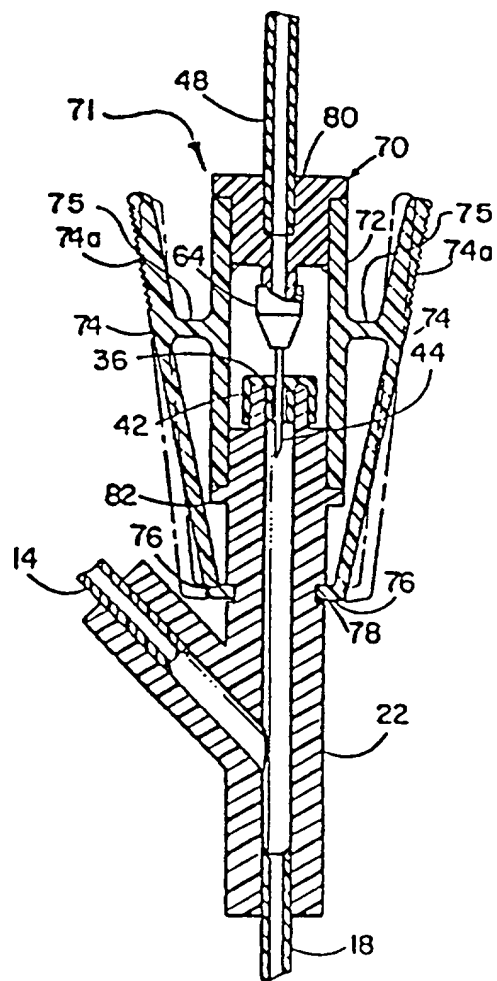


FIGURE 6

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FIGURE 7

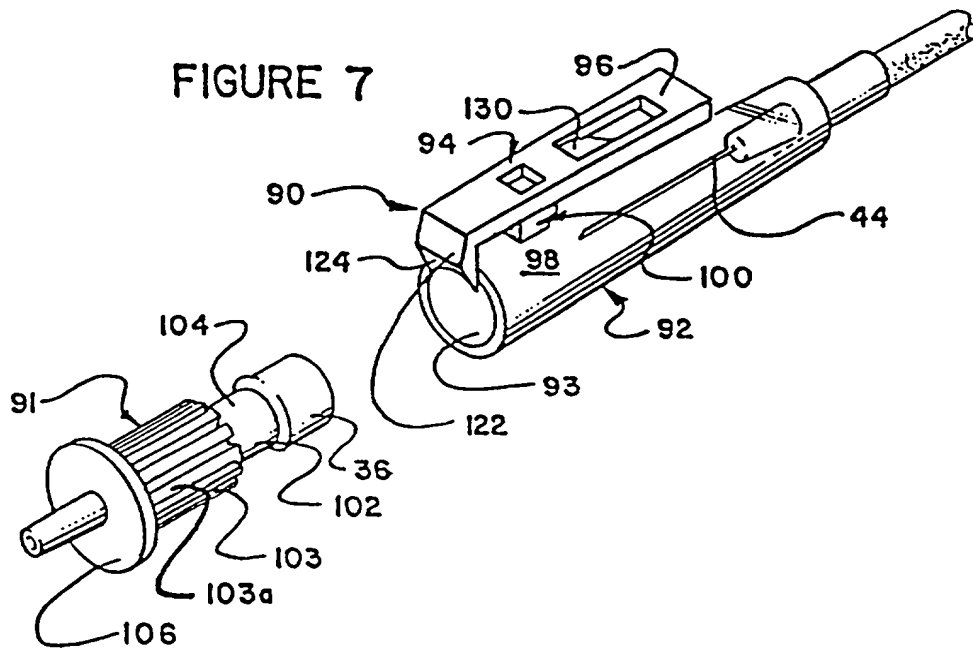
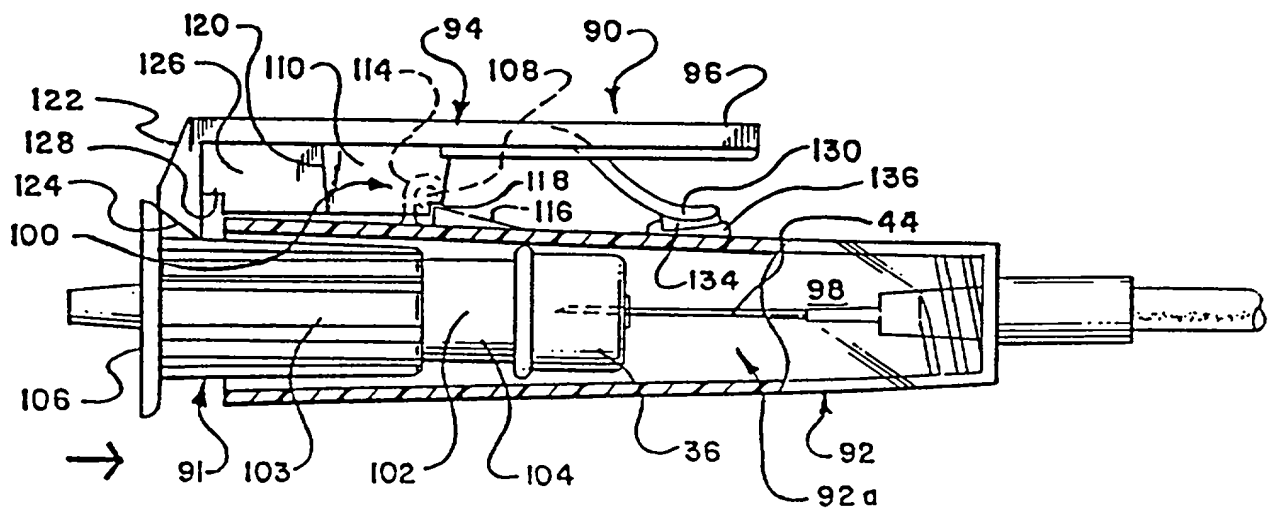


FIGURE 8



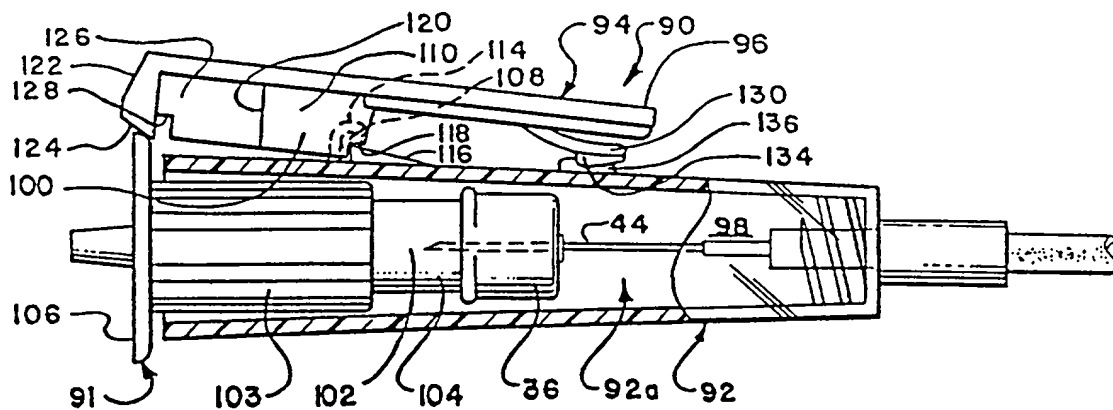


FIGURE 9

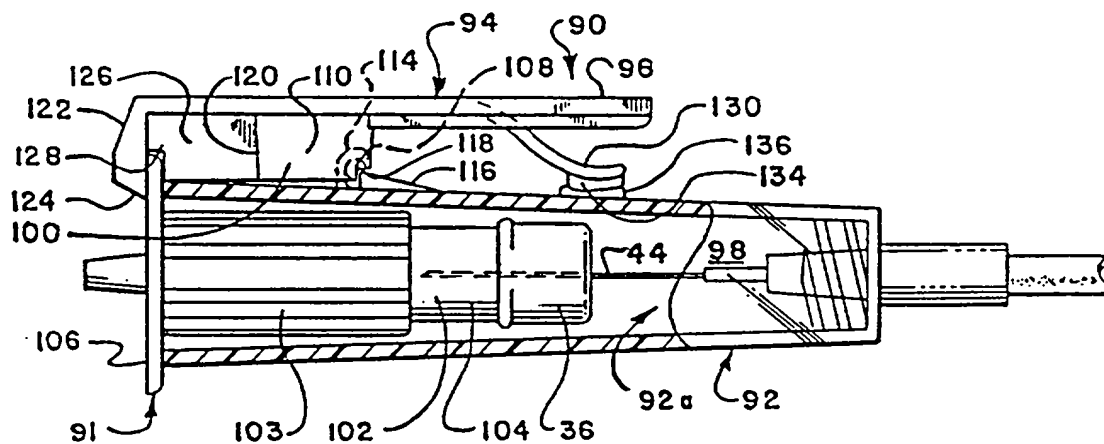


FIGURE 10

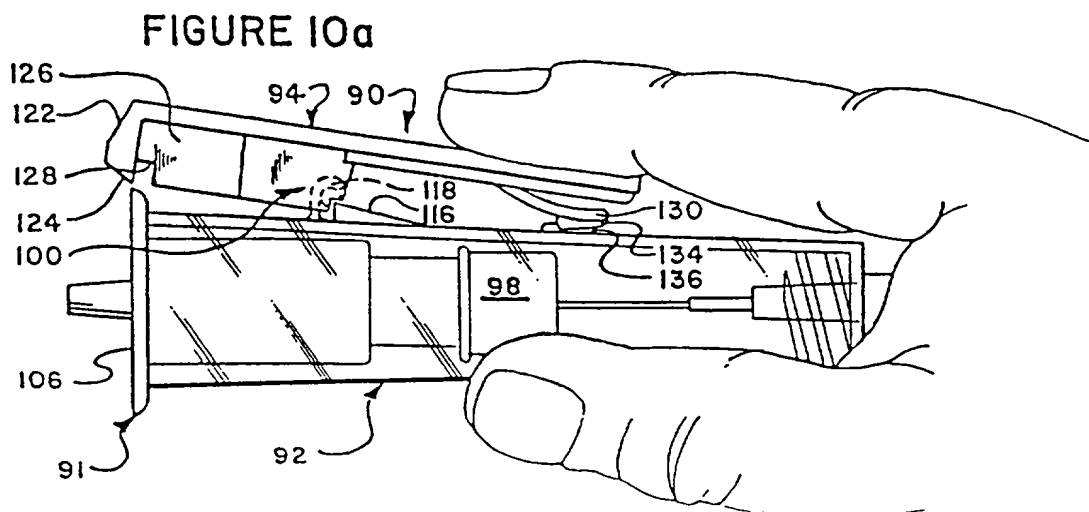


FIGURE 11

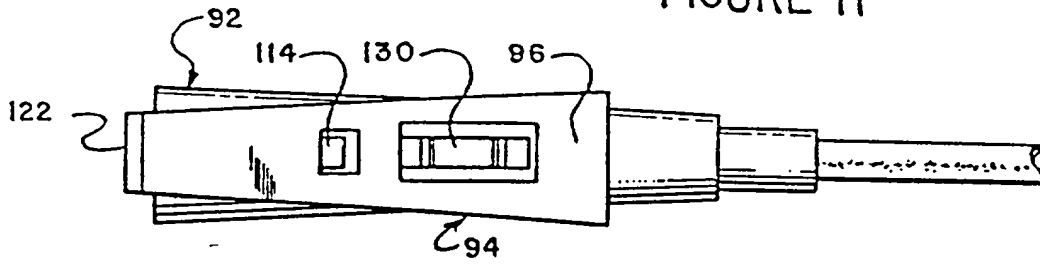


FIGURE 12

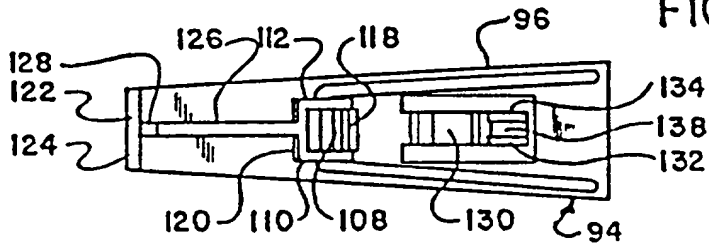


FIGURE 13

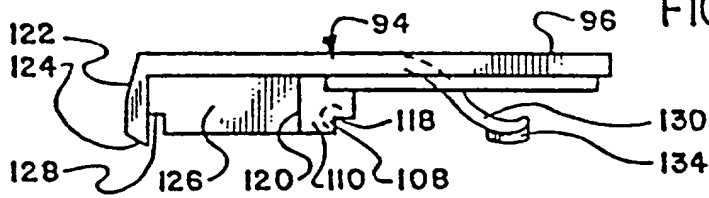


FIGURE 14

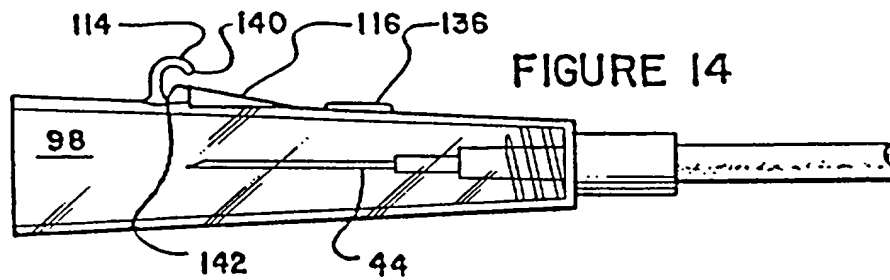


FIGURE 15

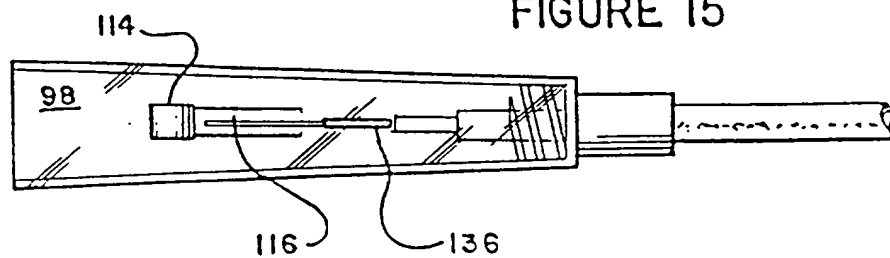


FIGURE 20

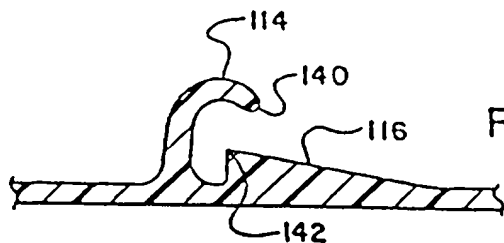
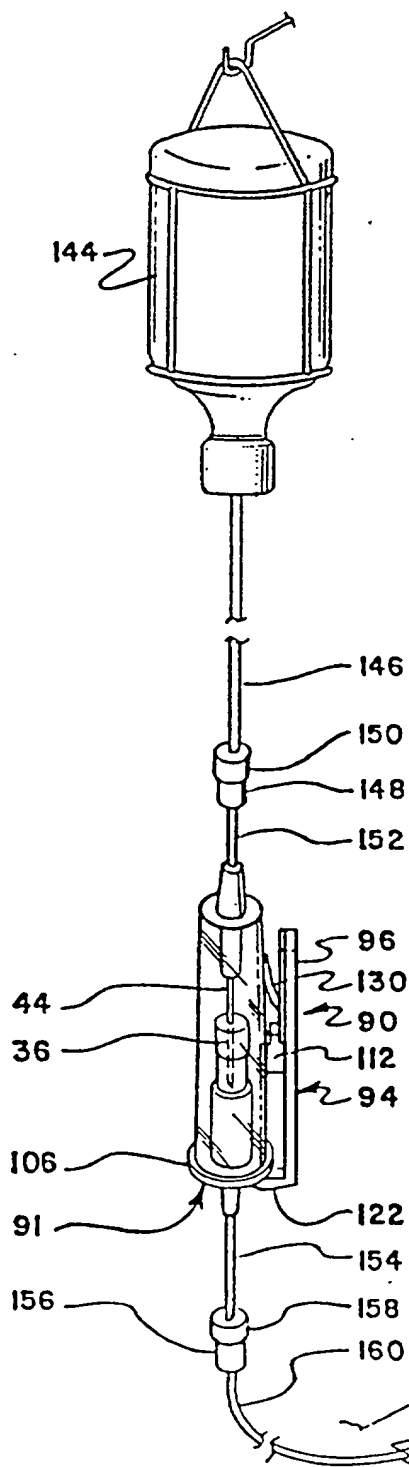


FIGURE 16

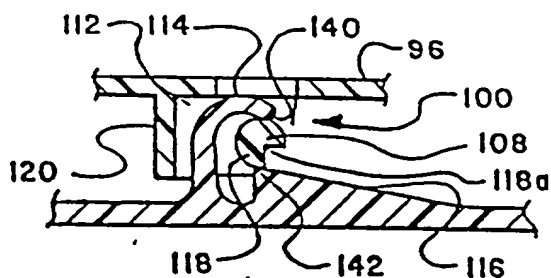


FIGURE 17

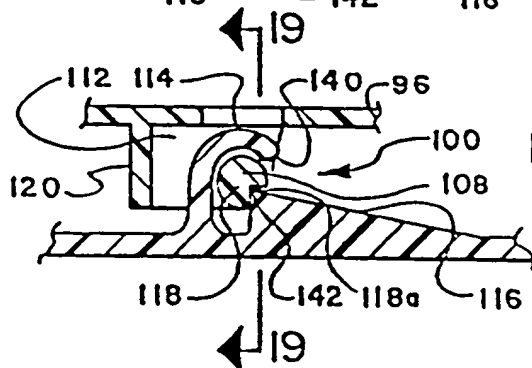


FIGURE 18

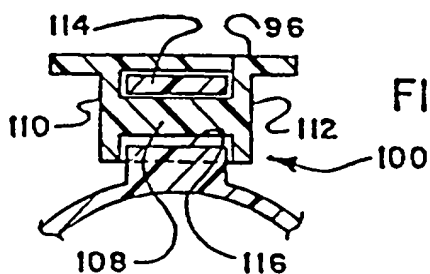


FIGURE 19

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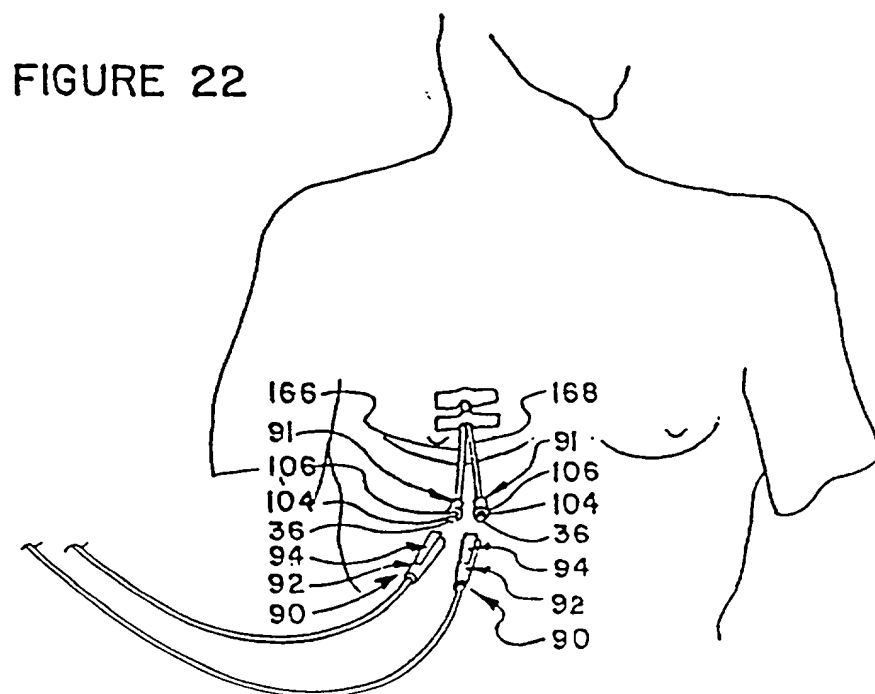
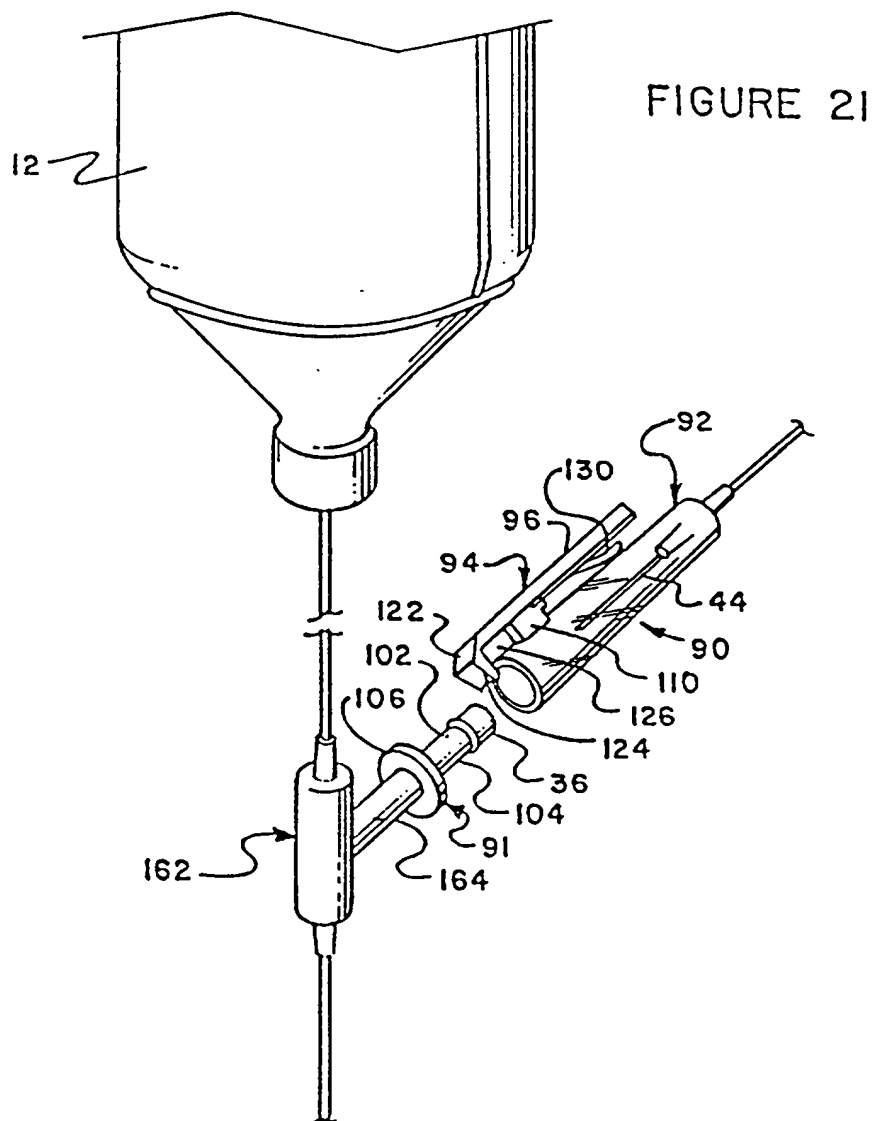


FIGURE 23

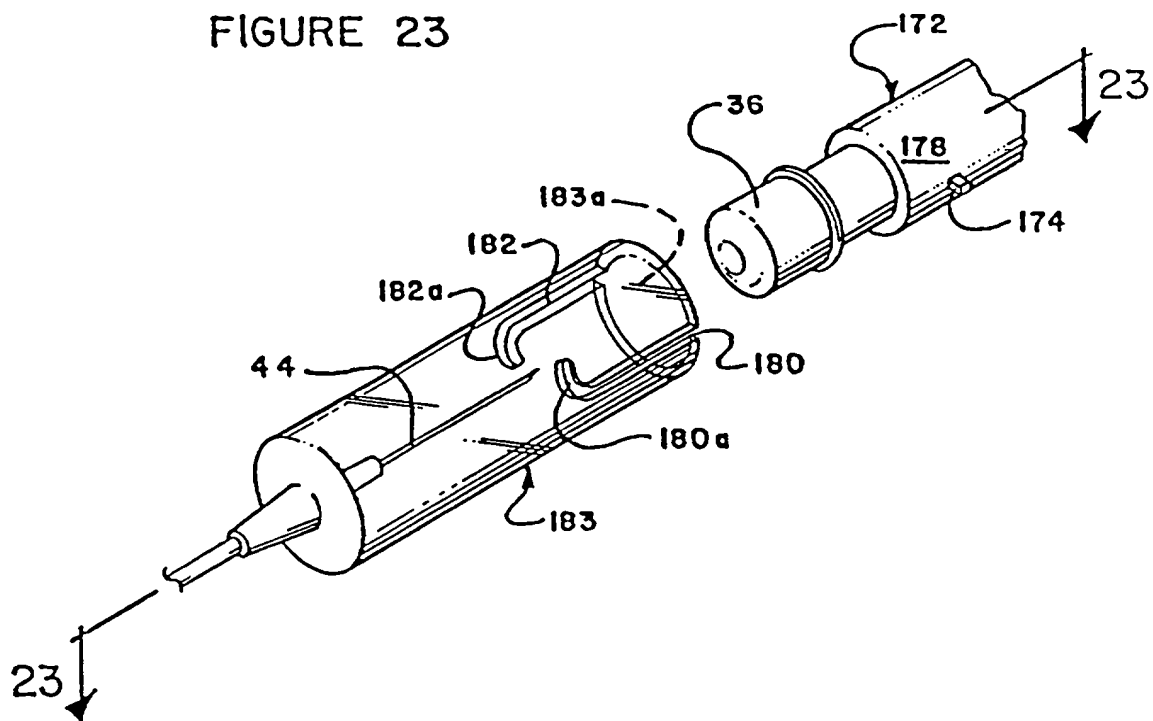
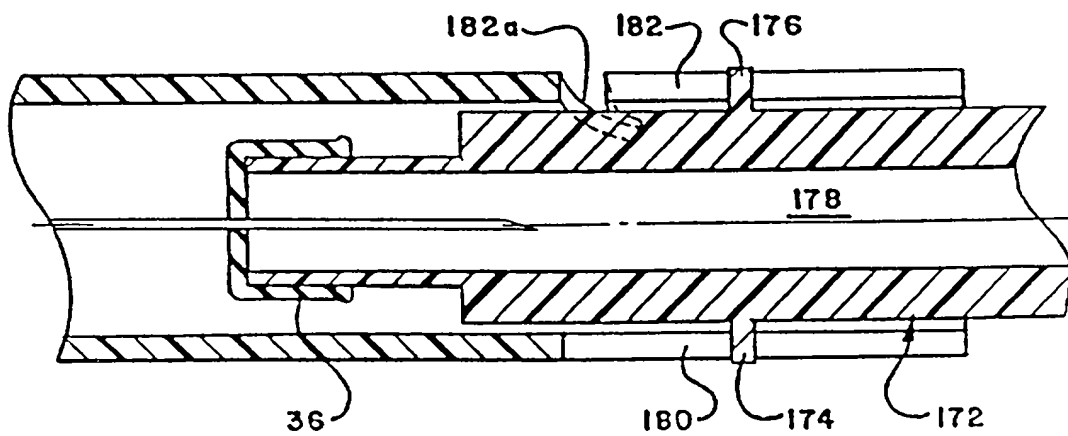


FIGURE 24



DECLARATION IN CONTINUATION-IN-PART APPLICATION

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I verily believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled:

MEDICAL CONNECTOR

described and claimed in the attached specification, that I understand the content of the attached specification, that this application in part discloses and claims subject matter disclosed in my earlier filed pending application, serial number 06/543,248, filed October 19, 1983, which was a continuation in part application of my earlier filed application 06/460,585, filed January 24, 1983; that I acknowledge my duty to disclose information of which I am aware which is material to the examination of this application, that, as to the subject matter of this application, which is common to said earlier application, I do not know and do not believe that the same was ever known or used in the United States of America before my invention thereof or patented or described in any printed publication in any country before my invention thereof or more than one year prior to said earlier in any country before my invention thereof or more than one year prior to said earlier application, or in public use or on sale in the United States of America more than one year prior to said earlier application, or in public use or on sale in the United States of America more than one year prior to said earlier application, or in public use or on sale in the United States of America more than one year prior to said earlier application; that said common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of said earlier application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to said earlier application; and that no application for patent or inventor's certificate on said invention has been filed by me or my representatives or assigns in any country foreign to the United States of America, except as follows:

Foreign Application(s), if any, for Patent or Inventor's Certificate Filed Within 12 Months Prior to the Filing Date of This Application:

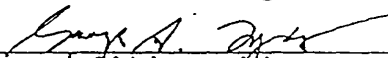
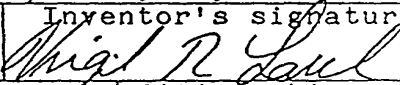
Country	Application No.	Date of Filing (day, month, year)	Priority Claimed Under 35 U.S.C. 1
<u>Japan</u>	<u>No. 8669/84</u>	<u>Jan 23, 1984</u>	Yes <u>x</u> No <u> </u>
<u>European Patent</u>	<u>No. 84100 561.4</u> <u>(Not known at</u> <u>this time)</u>	<u>Jan 19, 1984</u>	Yes <u>x</u> No <u> </u>
<u>Canada</u>	<u> </u>	<u>Jan 20, 1984</u>	Yes <u>x</u> No <u> </u>

that, as to the subject matter of this application which is not common to said earlier application, I do not know and do not believe that the same was ever known or used in the United States of America before my invention thereof or patented or described in any printed publication in any country before my invention thereof or more than one year prior to the date of this application, or in public use or on sale in the United States of America more than one year prior to the date of this application, and that subject matter has not been patented or made the subject of an inventor's certificate issued in any country foreign to the United States of America on an application filed by me or legal representatives or assigns more than twelve months prior to the date of this application; and that no application for patent or inventor's certificate on said invention has been filed by me or my representatives or assigns in any country foreign to the United States of America, except as follows:

All Foreign Applications, if any, for Patent or Inventor's Certificate Filed More Than 12 Months Prior To the Filing Date of This Application:

Country	Application No.	Date of Filing
None		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole or first inventor	Inventor's signature	Date
George A. Lopez		5/3/84
Residence	Citizenship	
3731 Seascapes Drive, Huntington Beach, CA	United States	
Post Office Address		
3731 Seascapes Drive, Huntington Beach, CA 92649		
Full name of sole or first inventor	Inventor's signature	Date
Virgil R. Laul		5/3/84
Residence	Citizenship	
38601 Via Corvalian, Dana Point, CA	United States	
Post Office Address		
38601 Via Corvalian, Dana Point, CA 92629		

Applicant or Patentee: ICU Medical, Inc.
Serial or Patent No.: _____
Date of Issuance: Filed May 3, 1984
Title: Medical Connector

Attorney's
Docket No.: 104

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN ICU Medical, Inc.
ADDRESS OF CONCERN 3731 Seascapes Drive
Huntington Beach, CA 92649

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of the United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average number of the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, titled Medical Connector
inventor(s) George A. Lopez and Virgil R. Lau
described in

- ☒ the specification filed herewith
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is stated below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

STATE OF _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

STATE OF _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to filing, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING George A. Lopez
TITLE OF PERSON OTHER THAN OWNER President
ADDRESS OF PERSON SIGNING 3731 Seascapes Drive
Huntington Beach, CA 92649

SIGNATURE [Signature] DATE May 3, 1984